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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/743,577	SCHLACHTER, HERBERT	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-13,17-19 and 22-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-13,17-19 and 22-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/17/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt for Amendments/Remarks received on 9/21/05 is acknowledged. Claims **2-13, 17-19 and 22-40** are pending in this application. Claims 1, 14-16, and 20-21 stand cancelled.

Withdrawn Rejections

The rejection of claims 2-13, 17-19 and 22-40 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments of 9/21/05.

The rejection of claims 2, 7-9, 11, 17, 18, 19, 30-35, and 38-40 under 35 U.S.C. 102(b) as being anticipated by Abad (5,538,740) is withdrawn in view of the amendments of 9/21/05.

The rejection of claims 2-9, 11, 13, 17-19, 22-35, and 38-40 under 35 U.S.C. 103(a) as being unpatentable over Hersh et al (5,667,791) is withdrawn in view of the amendments of 9/21/05.

The rejection of claims 2, 6-7, 9-12,17-19, 28-31, and 34-40 under 35 U.S.C. 103(a) as being unpatentable over Hillebrand (5,296,500) is withdrawn in view of the amendments of 9/21/05.

The rejection of claims 2-4, 6-7, 9-11, 13, 17-19, 22-25, 28-31, and 34-40 under 35 U.S.C. 103(a) as being unpatentable over Neigut (5,378,461) is withdrawn in view of the amendments of 9/21/05.

The rejection of claims 5 and 26-27 under 35 U.S.C. 103(a) as being unpatentable over Neigut (5,378,461) in view of Touzan et al (5,468,496) is withdrawn in view of the amendments of 9/21/05.

Information Disclosure Statement

The information disclosure statement filed 2/17/05 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered. It is noted that applicant has stated on the PTO-1449 form that a translation has been provided but the applicant has failed to submit a copy of the translation.

The other foreign documents listed in the PTO-1449 form have been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 40 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating skin irritations, sun burn, cellulites, wrinkles, acne, neurodermatitis, ozone damage, burns, caustic burns, thickening, edemas, hematomas, hemorrhoids, does not reasonably provide enablement for treating herpes, rheumatism, arthrosis, and skin cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement is considered in the view of the Wands factors (MPEP 2164.01 (a)). These include the nature of the claims, guidance of the specification, the existence of working

examples, predictability of the prior art, and state of the prior art. All of the Wands factors have been considered with the regard to the instant claims, with the most relevant discussed below.

Nature of the Invention: Rejected claim 40 is drawn to a method of treating skin irritations, sun burn, cellulites, wrinkles, acne, neurodermatitis, ozone damage, burns, caustic burns, thickening, edemas, herpes, hematomas, hemorrhoids, rheumatism, arthrosis, and skin cancer with a topical composition containing 1) an alkali or alkaline earth metal salts or other minerals, 2) at least one amino acid, 3) zinc oxide and an inorganic peroxide, 4) and a secondary plant substance.

Breath of the claims: The complex nature of the claims is greatly exacerbated by the breath of the claims. The invention encompasses treating a *divergent* skin disorders ranging from minor skin irritations to skin cancer, which are caused by unrelated factors, with one topical composition.

Guidance of the Specification: The guidance by the specification discloses that the individual "recipe" of the composition provides for a certain treatment. Thus, depending on the active agents added, the desired disorder will be treated. However, rejected claim 40 recites a generic composition of four broad elements to treat all the divergent skin diseases listed, whereas the specification states that the treatment depends on the recipe. Thus, the specification is limited, if not lacking, in guidance on the "recipe" that actually treats the skin disorder of choice. For instance, the specification does not provide one reasonable guidance on how to treat skin cancer, herpes, arthrosis, or rheumatism with the instant composition.

Working Examples: All of the working examples provided by the specification are directed towards the improvement of wrinkles and microcirculation. The examples do not speak

on the treatment of other divergent skin disorders such as skin cancer or herpes, with the generic composition.

The State of the Art: The prior art teaches various drugs to treat the divergent diseases listed in claim 40. For instance, the prior teaches the use of antivirals to treat herpes, however the instant invention claims to treat herpes without the requisite antiviral agents. Further, the art teaches the use of anti-inflammatories to treat rheumatism and arthrosis (a degenerative disease of the joints), which are both characterized by pain and inflammation of the joints. Lastly, the prior art teaches the use of cytoxic drugs, i.e. neoplastic agents, anticancer agents, etc., to treat skin cancer. Thus, it can be seen that the composition that is directed to treating these disorders does not have the requisite drug to treat the skin disorder.

Undue Experimentation: The instant invention requires undue experimentation to find the appropriate "recipe" to treat the appropriate disease. Firstly, there is a multitude of possible combinations of the optional ingredients in the specification. Thus, a skilled artisan would first need to ascertain the appropriate combination of components in the exahasitive list in the specification, then a skilled artisan would need to test the each possible combination, and the skin disease and ascertain which skin disorder, the combination treats. Thus, the instant invention requires undue experimentation for a skilled artisan to practice the invention.

Response to Arguments

Applicant argues that Watzl et al disclose the use of the instantly claimed secondary plant substances (SPS) to treat herpes. Applicant argues that certain SPS have anticarcinogenic effects to treat skin cancer. Applicant argues that certain polyphenols and sulfides also have anti-inflammatory effects to treat rheumatism and arthrosis. Lastly, applicant argues that

polyunsaturated fatty acids as recited in claim 3 have inflammatory effects to treat rheumatism and arthrosis.

Applicant's arguments filed 9/21/05 have been fully considered but they are not persuasive. The examiner notes that the applicant has not provided the non-patent literature, Watzl et al, to consider. Thus, the rejection is maintained until applicant submits the article that the arguments are based on.

Response to Arguments

Applicant's arguments with respect to the prior art rejections have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 5-11, 17-19, 26-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murad (5,962,517) in view of Oliver (5,869,062).

Murad teaches a pharmaceutical composition for the **treatment of acne** having an acne reduction component in an amount sufficient to reduce the redness and blemishes associated with acne. See abstract. Suitable routes for administration of the composition include oral, rectal, parenteral, intravenous, **topical**, transdermal, subcutaneous, and intramuscular. The composition is formulated as creams, pastes, gels, or ointments, or as a solution or a suspension in an aqueous liquid, a non-aqueous liquid, an oil-in-water emulsion, or a water-in-oil liquid emulsion. See column 10, lines 40-55. The pharmaceutical composition comprises an acne reduction component comprising 1) at least one of a **zinc compound** or a Vitamin A source; 2) at least one of burdock root yellow dock root or a **catechin**-based composition (instant **flavonoid**); 3) and a skin cell conditioning component comprising a transition metal other than zinc. See claim 1.

The acne reduction component is a vitamin A source in the amount of 0.1-2%, a zinc component in the amount of 0.1-25%, or a carotenoid in the amount of 0.1-10%. The acne reduction components may be used in mixtures. See examples and claim 5. The zinc component of the pharmaceutical composition reduces the inflammation associated with acne. Furthermore, the ability of zinc to aid in wound healing, immune response, tissue regeneration, and utilization of vitamin A make it an effective component in the composition and for the treatment of acne according to the invention. The zinc component may be any zinc compound or pharmaceutically acceptable salt thereof. See column 5, lines 39-55.

The skin cell conditioning component comprises a transition metal complex with an organic compound in the amount of 0.001-5%. In the more preferred embodiment, the transition metal comprises **chromium (trace mineral)** and the complex is present in about 0.001 to 5 weight percent of the pharmaceutical composition. The catechin-based composition is

proanthocyanidin present in about 0.1 to 15% and the yellow dock root is present in about 1 to 20%. See column 4, lines 5-30 and column 7, lines 53-65. .

Murad teaches a preferred composition wherein the composition further comprises 1 to 30% of an amino acid component such as **L-lysine** and **L-proline**, 1 to 20% of a magnesium component such as **magnesium oxide**, and 0.05 to 10% of a selenium component wherein the selenium is complexed to an amino acid to facilitate the repair of skin damaged by acne. See column 8, lines 34-50. Murad teaches the use of organic acids such as glycolic or salicylic acid in the composition. see column 10, lines 5-10. Note that organic acids are astringent components.

Example 3 teaches a pharmaceutical composition comprising 13.4% vitamin E, 13.2% L-lysine hydrochloride, 13% **calcium** ascorbate, burdock root, yellow dock, 10.6% **L-proline**, horsetail extract (an antibiotic), **7% magnesium oxide**, 2.1% zinc ascorbate, 1.3% vitamin B6, 1.1% **grape seed extract (source of flavonoid proanthocyanidins)**, Vitamin B3, Vitamin B2, Vitamin B1, Vitamin B5, **0.5% chromium**, and 0.2% vitamin A.

Firstly, although Murad teaches a zinc component, Murad does not teach zinc oxide in particular and secondly Murad does not teach an inorganic peroxide.

Oliver teaches a skin treatment composition comprising calamine (which is zinc oxide with approximately 0.5% ferric oxide) in an amount between about 8% and 20%, an antioxidant in an amount between about 0.05 and 3%; and an herbal anti-bacterial substance in an amount between about 0.25 and 4%. See abstract. These skin-related problems include acne, rashes, blemishes, skin bites, razor irritation, athlete's foot, and general itching. See column 1, lines 7-10.

Oliver teaches using calamine for reducing inflammation, redness and itching, as well as for drying out excess oils and fluids. See column 2, lines 14-20. The second critical component is at least one anti-oxidant, which prevents free radical damage. Suitable anti-oxidants include Vitamin C (ascorbic acid between 0.45 and 2 weight percent), Vitamin E (between 0.08 and 1.0 weight percent) and beta-carotene (Vitamin A). See column 2, lines 20-30. The third critical component is a naturally occurring anti-bacterial product in treating infections. Suitable naturally occurring anti-bacterial products include naturally occurring herbs selected from golden seal extract, tea tree oil, echinacea, garlic, and red clover. The preferred anti-bacterial products are golden seal extract (0.35-0.90%) and tea tree oil (1 to 3%). Oliver teaches the additional use of an astringent such as witch hazel and alpha hydroxy acids. The preferred astringent is witch hazel and the preferred range of the astringent is in an amount between about 1 and 12 %. See column 2, lines 57-65. Olive teaches the use of a peroxide in an amount between about 3 and 8%, which to help treat any infection. Suitable peroxides include hydrogen peroxide. Zinc oxide in the amount of 8-20% also is taught as an additional base. Specifically the composition taught on column 3 comprises water, 20% glycerin, 18% calamine, 18% **zinc oxide**, 5% witch hazel, .88% ascorbic acid, 5% **peroxide**, 2% golden seal, .70% tea tree oil, and .16% vitamin E.

Firstly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings Murad and Oliver and utilize a peroxide such as hydrogen peroxide (inorganic peroxide). One would have been motivated to utilize a peroxide to treat any infections that arise as taught by Oliver. Secondly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize zinc oxide as the zinc component taught in Murad. One would have been motivated to do so with a reasonable

expectation of success since Oliver teaches calamine (zinc oxide with 0.5% ferric oxide) reduces inflammation and redness and Murad teaches the function of the zinc component is to reduce the inflammation associated with acne. Further, a skilled artisan would have reasonably expectation of similar results by the use of zinc oxide as the zinc component since although Murad prefers zinc ascorbate, Murad teaches *any* zinc compound or pharmaceutically acceptable salt thereof may be used and zinc itself has the ability to aid in wound healing, immune response, and tissue regeneration. Additionally, Oliver also teaches the use of zinc oxide (not in the form of calamine) as additional base in the composition. Therefore, alternatively a skilled artisan would have been motivated to add zinc oxide in Murad's composition when formulating a topical composition since zinc oxide acts as a base (carrier).

Claims 3-4, 13, and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murad (5,962,517) in view of Oliver (5,869,062) in further view of Horrobin (5,145,686).

The teachings of Murad have been set forth above, in particular Murad teaches a pharmaceutical composition for the **treatment of acne** having an acne reduction component in an amount sufficient to reduce the redness and blemishes associated with acne. See abstract. The teachings of Oliver have been set forth above, in particular Oliver teaches a skin treatment composition comprising calamine (which is zinc oxide with approximately 0.5% ferric oxide) in an amount between about 8% and 20%, an antioxidant in an amount between about 0.05 and 3%; and an herbal anti-bacterial substance in an amount between about 0.25 and 4%. Oliver also teaches the use of peroxides in treating infections.

The combined references do not teach the use of a polyunsaturated fatty acid.

Horrobin et al teach a topical pharmaceutical composition containing vegetable oils for treating skin inflammation. The reference teaches linoleic acid from vegetable sources has anti-inflammatory properties (col. 2, lines 30) and can be used to treat skin disorders such as burn and wounds (col. 4, lines 13-24). Further, Horrobin et al teach the use of zinc or zinc salts for the bioconversion of linoleic acid and its own healing properties (col. 5, lines 3-14). Horrobin et al suggest the use of lysine in the composition (col. 3, lines 56-60).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Murad, Oliver, and Horrobin et al and additionally utilize polyunsaturated fatty acid. One would be motivated to use fatty acids since Horrobin et al teach polyunsaturated fatty acids such as linoleic acid have anti-inflammatory properties. Therefore, a skilled artisan would have been motivated to additionally add a polyunsaturated fatty acid for its additive effect of treating skin inflammation.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Murad (5,962,517) in view of Oliver (5,869,062) in further view of Horrobin (5,145,686) in further view of Burke et al (5,693,318).

The teachings of Murad have been set forth above, in particular Murad teaches a pharmaceutical composition for the **treatment of acne** having an acne reduction component in an amount sufficient to reduce the redness and blemishes associated with acne. See abstract. The teachings of Oliver have been set forth above, in particular Oliver teaches a skin treatment composition comprising calamine (which is zinc oxide with approximately 0.5% ferric oxide) in an amount between about 8% and 20%, an antioxidant in an amount between about 0.05 and 3%; and an herbal anti-bacterial substance in an amount between about 0.25 and 4%. Oliver also

teaches the use of peroxides in treating infections. The teachings of Horrobin have been set forth above, in particular Horrobin teaches the use of polyunsaturated fatty acids.

The combined references do not teach the instant peroxides claimed.

Burke teaches a salicylic acid, which acts as a keratolytic agent, and peroxide compounds which acts as an antiseptic for disinfecting the skin. See abstract and column 1, lines 15-30. Burke teaches peroxides useful include hydrogen peroxide, zinc peroxide, sodium peroxide. The peroxides are used at a preferred level of 0.5 to 5% by weight, a more preferred level of 0.5 to 3% by weight and a most preferred level of 1 to 2% by weight. See column 5, lines 35-50.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Murad, Oliver, and Horrobin et al, and Burke and substitute hydrogen peroxide with the instantly claimed peroxides. One would have been motivated to do so with the reasonable expectation of similar results since Burke teaches hydrogen peroxide and the instantly claimed peroxides all function as disinfectants and may be used topically to treat the skin. Therefore, it prima facie obvious to substitute one equivalent component for another equivalent with the expectation of similar results since the art clearly establishes functional equivalency, i.e. the pharmacological property of acting as a disinfectant when topically applied.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER